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Actavis Pharma, Inc.*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

ACTAVIS LABORATORIES FL, INC. and
ACTAVIS PHARMA, INC.,

Defendants.

Civil Action No.: 15-6934 (SRC/CLW)

**DEFENDANTS ACTAVIS
LABORATORIES FL, INC.'S AND
ACTAVIS PHARMA, INC.'S ANSWER,
DEFENSES, AND COUNTERCLAIMS**

In response to the Complaint filed by Plaintiff Impax Laboratories, Inc. (“Impax”), Defendants Actavis Laboratories FL, Inc. (“Actavis FL”) and Actavis Pharma, Inc. (collectively, “Defendants”), through their attorneys, hereby submit their Answer, Defenses, and Counterclaims.

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Defendants deny that Plaintiff is entitled to the relief requested or any other relief.

Defendants, through their attorneys, answer as follows:

NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to state claims arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. Defendants further admit that it has submitted an Abbreviated New Drug Application (“ANDA”) seeking approval to market carbidopa and levodopa extended release capsules prior to the expiration of U.S. Patent Nos. 7,094,427, 8,377,474, 8,454,998, 8,557,283, 9,089,607, and 9,089,608. Otherwise denied.

THE PARTIES

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny each and every allegation in paragraph 2 on that basis.

3. Defendants admit that Actavis FL is a corporation organized and existing under the laws of the state of Florida. Otherwise denied.

4. Defendants admit that Actavis FL is in the business of manufacturing pharmaceutical products. Otherwise denied.

5. Defendants admit that Actavis Pharma, Inc. is a corporation organized and existing under the laws of Delaware, and has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Otherwise denied.

6. Defendants admit that Actavis Pharma, Inc. is in the business of marketing and distributing pharmaceutical products, including pharmaceutical products manufactured by Actavis FL. Otherwise denied.

7. Denied.

8. Defendants admit that the Complaint purports to refer to Actavis FL and Actavis Pharma, Inc. collectively as “Actavis.” Otherwise denied.

JURISDICTION AND VENUE

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to state claims arising under the patent laws of the United States, and that this Court has subject matter jurisdiction over the action. Otherwise denied.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, Defendants do not contest venue in this Court. Otherwise denied.

PERSONAL JURISDICTION OVER ACTAVIS FL

11. Defendants repeat and incorporate here by reference their responses to paragraphs 1-10.

12. Defendants admit that Actavis FL manufactures pharmaceutical products. Otherwise denied.

13. Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, Actavis FL does not contest personal jurisdiction for any claims properly before this Court. Otherwise denied.

14. Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL did not contest jurisdiction in this judicial district for the purposes of certain prior litigations. Otherwise denied.

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Offer for Confidential Access for ANDA No. 208522 included in its letters to Impax dated August 4, 2015, and August 13, 2015, indicated that “[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey.” Otherwise denied.

PERSONAL JURISDICTION OVER ACTAVIS PHARMA

16. Defendants repeat and incorporate here by reference their responses to paragraphs 1-15.

17. Defendants admit that Actavis Pharma, Inc. distributes pharmaceutical products. Otherwise denied.

18. Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, Actavis Pharma, Inc. does not contest personal jurisdiction for any claims properly before this Court. Otherwise denied.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis Pharma, Inc. did not contest jurisdiction in this judicial district for the purposes of certain prior litigations. Otherwise denied.

BACKGROUND

U.S. Patent No. 7,094,427

20. Defendants admit that the face of the '427 patent lists the title as "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms," identifies the issue date as August 22, 2006, and identifies Chien-Hsuan Han, Larry Hsu, and Ann F. Hsu as inventors. Defendants further admit that Exhibit 1 to the Complaint purports to be a copy of the '427 patent. Otherwise denied.

U.S. Patent No. 8,377,474

21. Defendants admit that the face of the '474 patent lists the title as "Controlled Release Formulations of Levodopa and Uses Thereof," identifies the issue date as February 19, 2013, and identifies Ann Hsu, Jim H. Kou, and Laman Alani as inventors. Defendants further admit that Exhibit 2 to the Complaint purports to be a copy of the '474 patent. Otherwise denied.

U.S. Patent No. 8,454,998

22. Defendants admit that the face of the '998 patent lists the title as "Controlled Release Formulations of Levodopa and Uses Thereof," identifies the issue date as June 4, 2013, and identifies Ann Hsu, Jim H. Kou, and Laman Alani as inventors. Defendants further admit that Exhibit 3 to the Complaint purports to be a copy of the '998 patent. Otherwise denied.

U.S. Patent No. 8,557,283

23. Defendants admit that the face of the '283 patent lists the title as "Controlled Release Formulations of Levodopa and Uses Thereof," identifies the issue date as October 15, 2013, and identifies Ann Hsu, Jim H. Kou, and Laman Lynn Alani as inventors. Defendants further admit that Exhibit 4 to the Complaint purports to be a copy of the '283 patent. Otherwise denied.

U.S. Patent No. 9,089,607

24. Defendants admit that the face of the '607 patent lists the title as "Controlled Release Formulations of Levodopa and Uses Thereof," identifies the issue date as July 28, 2015, and identifies Ann Hsu, Jim H. Kou, and Laman Lynn Alani as inventors. Defendants further admit that Exhibit 5 to the Complaint purports to be a copy of the '607 patent. Otherwise denied.

U.S. Patent No. 9,089,608

25. Defendants admit that the face of the '608 patent lists the title as "Controlled Release Formulations of Levodopa and Uses Thereof," identifies the issue date as July 28, 2015, and identifies Ann Hsu, Jim H. Kou, and Laman Lynn Alani as inventors. Defendants further admit that Exhibit 6 to the Complaint purports to be a copy of the '608 patent. Otherwise denied.

RYTARY®

26. Defendants admit that the Approved Drug products with Therapeutic Equivalence Evaluations (“the Orange Book”) identifies Impax as the holder of NDA No. 203312 for Rytary® (carbidopa/levodopa) extended release capsules, for oral use, 23.75 mg/95 mg, 36.23 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them.

27. Admitted.

28. Defendants admit that the Orange Book lists the ’427, ’474, ’998, ’283, ’607, and ’608 patents with respect to Rytary®. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE ’247 PATENT BY ACTAVIS

29. Defendants repeat and incorporate here by reference their responses to paragraphs 1-28.

30. Defendants admit that Actavis FL submitted ANDA No. 208522 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market carbidopa/levodopa extended release capsules, for oral use, in 23.75 mg/95 mg, 36.23 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg dosages. Otherwise denied.

31. Defendants admit that ANDA No. 208522 identifies Rytary® as the reference listed drug, contains studies that indicate that the 61.25 mg / 245 mg strength of carbidopa and

levodopa extended-release capsules described therein are bioequivalent to the reference listed drug, and requests an *in vivo* bioequivalence waiver with respect to the 23.75 mg/95 mg, 36.23 mg/145 mg, 48.75 mg/195 mg dosage strengths. Otherwise denied.

32. Defendants admit that Actavis FL sent letters to Impax on August 4, 2015, and August 13, 2015, stating that Actavis FL had included Paragraph IV certifications in ANDA No. 208522 that the '424, '474, '998, '283, '607, and '608 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the products described therein. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them.

33. Denied.

34. Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

COUNT II – INFRINGEMENT OF THE '474 PATENT BY ACTAVIS

43. Defendants repeat and incorporate here by reference their responses to paragraphs 1-42.

44. Denied.

45. Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

COUNT III – INFRINGEMENT OF THE '998 PATENT BY ACTAVIS

54. Defendants repeat and incorporate here by reference their responses to paragraphs 1-53.

55. Denied.

56. Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

COUNT IV – INFRINGEMENT OF THE '283 PATENT BY ACTAVIS

65. Defendants repeat and incorporate here by reference their responses to paragraphs 1-64.

66. Denied.

67. Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

COUNT V – INFRINGEMENT OF THE '607 PATENT BY ACTAVIS

76. Defendants repeat and incorporate here by reference their responses to paragraphs 1-75.

77. Denied.

78. Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT VI – INFRINGEMENT OF THE '608 PATENT BY ACTAVIS

87. Defendants repeat and incorporate here by reference their responses to paragraphs 1-86.

88. Denied.

89. Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Actavis FL filed ANDA No. 208522, seeking approval to market the products described therein. Otherwise denied.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any of the relief sought in the prayer for relief or any relief whatsoever.

AFFIRMATIVE AND SEPARATE DEFENSES

First Defense (Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

Second Defense (Non-infringement of the '427 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '427 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Third Defense
(Invalidity and/or Unenforceability of the '427 Patent)

Each and every claim of the '427 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Each and every claim of the '427 patent is also invalid and/or unenforceable for reasons of abandonment, waiver, surrender, intervening rights, and/or estoppel.

Fourth Defense
(Non-infringement of the '474 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '474 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Fifth Defense
(Invalidity of the '474 Patent)

Each and every claim of the '474 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Sixth Defense
(Non-infringement of the '998 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '998 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Seventh Defense
(Invalidity of the '998 Patent)

Each and every claim of the '998 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Eighth Defense
(Non-infringement of the '283 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '283 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Ninth Defense
(Invalidity of the '283 Patent)

Each and every claim of the '283 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Tenth Defense
(Non-infringement of the '607 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '607 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Eleventh Defense
(Invalidity of the '607 Patent)

Each and every claim of the '607 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Twelfth Defense
(Non-infringement of the '608 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '608 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Thirteenth Defense
(Invalidity of the '608 Patent)

Each and every claim of the '608 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

Fourteenth Defense
(No costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

Fifteenth Defense
(Reservation of rights)

Defendants reserve the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiff other than those expressly admitted herein, and without prejudice of the rights of Defendants to plead additional Counterclaims as the facts of the matter warrant, Actavis FL hereby asserts the following Counterclaims against Impax.

THE PARTIES

1. Actavis FL is a corporation organized and existing under the laws of the State of Florida, having a place of business at 2945 W. Corporate Lakes Blvd., Weston, FL 33331.

2. Upon information and belief, Impax is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

JURISDICTION AND VENUE

3. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. Personal jurisdiction over Impax is proper because, *inter alia*, Impax initiated and is prosecuting this action, and because, upon information and belief, either directly or through its agents, it transacts business in, and derives substantial revenue from, New Jersey.

5. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

6. U.S. Patent No. 7,094,427 (“the ’427 patent”) is entitled “Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms,” and states that it was issued on August 22, 2006.

7. U.S. Patent No. 8,377,474 (“the ’474 patent”) is entitled “Controlled Release Formulations of Levodopa and Uses Thereof,” and states that it was issued on February 19, 2013.

8. U.S. Patent No. 8,454,998 (“the ’998 patent”) is entitled “Controlled Release Formulations of Levodopa and Uses Thereof,” and states that it was issued on June 4, 2013.

9. U.S. Patent No. 8,557,283 (“the ’283 patent”) is entitled “Controlled Release Formulations of Levodopa and Uses Thereof,” and states that it was issued on October 15, 2013.

10. U.S. Patent No. 9,089,607 (“the ’607 patent”) is entitled “Controlled Release Formulations of Levodopa and Uses Thereof,” and states that it was issued on July 28, 2015.

11. U.S. Patent No. 9,089,608 (“the ’608 patent”) is entitled “Controlled Release Formulations of Levodopa and Uses Thereof,” and states that it was issued on July 28, 2015.

12. Upon information and belief, Impax is the owner of the ’427, ’474, ’998, ’283, ’607, and ’608 patents.

13. Upon information and belief, Impax is the holder of New Drug Application (“NDA”) No. 203312 for Rytary® (carbidopa/levodopa) extended release capsules, 23.75 mg/95 mg, 36.23 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg.

14. The '427, '474, '998, '283, '607, and '608 patents are listed in the Approved Drug products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 203312.

15. Actavis FL submitted Abbreviated New Drug Application ("ANDA") No. 208522 to the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of carbidopa and levodopa extended release capsules prior to the expiration of U.S. Patent Nos. 7,094,427, 8,377,474, 8,454,998, 8,557,283, 9,089,607, and 9,089,608. Actavis Pharma, Inc. has not submitted an ANDA under 21 U.S.C. § 355(j), or an NDA under 21 U.S.C. § 355(b)(2), seeking approval for the commercial manufacture, use, or sale in the United States of carbidopa and levodopa extended release capsules prior to the expiration of U.S. Patent Nos. 7,094,427, 8,377,474, 8,454,998, 8,557,283, 9,089,607, or 9,089,608.

16. ANDA No. 208522 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '424, '474, '998, '283, '607, and '608 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of the products described therein. Actavis Pharma, Inc. has not certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '424, '474, '998, '283, '607, or '608 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of the products described in ANDA No. 208522.

17. Actavis FL sent notice of its certification to Impax on or about August 4, 2015, and August 13, 2015. Upon information and belief, Impax received those notifications.

18. On September 17, 2015, Impax filed this lawsuit alleging infringement of the '424, '474, '998, '283, '607, and '608 patents.

19. ANDA No. 208522 has not received either tentative or final approval, and neither Actavis Pharma FL nor Actavis Pharma, Inc. has engaged in the manufacture, use, sale, offer for sale in the United States, or importation into the United States, of carbidopa and levodopa extended release capsules, for commercial purposes. Nonetheless, a justiciable controversy exists as to the infringement and validity of the '424, '474, '998, '283, '607, and '608 patents because Impax brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of ANDA No. 208522 would infringe those patents, and Actavis FL has denied the alleged infringement and further alleges that the claims of the '424, '474, '998, '283, '607, and '608 patents are invalid. This controversy is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY AND/OR UNENFORCEABILITY
OF THE '427 PATENT

20. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-19 of these Counterclaims.

21. Each and every claim of the '427 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '427 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '427 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '427 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '427 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '427 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '427 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '427 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '427 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '427 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '427 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

22. The '427 patent is the subject of *Ex Parte* Reexamination No. 90/012,293 ("the '293 reexamination") currently pending in the United States Patent Office.

23. All of the original claims of the '427 patent have been rejected during the '293 reexamination.

24. In response to the rejections, Impax has amended and/or cancelled all of the original claims of the '427 patent during the '293 reexamination. The amended claims each contain new substantive limitations that were not present in the original claims that were subject to the reexamination. Each of these amended claims of the '427 patent currently stand rejected in the reexamination. Impax has appealed the rejection of the amended claims to the Patent Trial and Appeal Board. That appeal is pending.

25. Actavis FL is entitled to a judicial declaration that all claims of the '427 patent are invalid or unenforceable.

COUNT II
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '427 PATENT

26. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-25 of these Counterclaims.

27. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '427 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

28. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '427 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '427 patent.

COUNT III
DECLARATORY JUDGMENT OF INVALIDITY OF THE '474 PATENT

29. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-28 of these Counterclaims.

30. Each and every claim of the '474 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '474 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '474 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '474 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '474 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '474 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '474 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '474 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '474 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '474 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '474 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

31. Actavis FL is entitled to a judicial declaration that all claims of the '474 patent are invalid.

**COUNT IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '474 PATENT**

32. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-31 of these Counterclaims.

33. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '474 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

34. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '474 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '474 patent.

**COUNT V
DECLARATORY JUDGMENT OF INVALIDITY OF THE '998 PATENT**

35. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-34 of these Counterclaims.

36. Each and every claim of the '998 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '998 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '998 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '998 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '998 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '998 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '998 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '998 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '998 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '998 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '998 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

37. Actavis FL is entitled to a judicial declaration that all claims of the '998 patent are invalid.

COUNT VI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '998 PATENT

38. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-37 of these Counterclaims.

39. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '998 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

40. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '998 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '998 patent.

COUNT VII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '283 PATENT

41. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-40 of these Counterclaims.

42. Each and every claim of the '283 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '283 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '283 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '283 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '283 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '283 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '283 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '283 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '283 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '283 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '283 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

43. Actavis FL is entitled to a judicial declaration that all claims of the '283 patent are invalid.

COUNT VIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '283 PATENT

44. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-43 of these Counterclaims.

45. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '283 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

46. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '283 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '283 patent.

COUNT IX
DECLARATORY JUDGMENT OF INVALIDITY OF THE '607 PATENT

47. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-46 of these Counterclaims.

48. Each and every claim of the '607 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '607 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '607 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '607 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '607 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '607 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '607 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '607 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '607 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '607 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '607 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

49. Actavis FL is entitled to a judicial declaration that all claims of the '607 patent are invalid.

COUNT X
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '607 PATENT

50. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-49 of these Counterclaims.

51. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '607 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

52. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '607 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '607 patent.

COUNT XI
DECLARATORY JUDGMENT OF INVALIDITY OF THE '608 PATENT

53. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-52 of these Counterclaims.

54. Each and every claim of the '608 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting, the bases for which include:

(a) The alleged invention of the '608 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '608 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(c) The '608 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '608 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '608 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '608 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '608 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The subject matter claimed in the '608 patent is invalid for obviousness-type double patenting in that any differences between the subject matter claimed in the patent and the subject matter claimed in any other earlier expiring patent with a common owner would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(g) The '608 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(h) The claims of the '608 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

55. Actavis FL is entitled to a judicial declaration that all claims of the '608 patent are invalid.

COUNT XII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '608 PATENT

56. Actavis FL re-alleges and incorporates by reference the allegations in paragraphs 1-55 of these Counterclaims.

57. Actavis FL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '608 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

58. Actavis FL is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '608 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 208522 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '608 patent.

COUNTERCLAIM PLAINTIFF'S PRAYER FOR RELIEF

Wherefore, Actavis FL respectfully requests that this Court enter judgment in its favor and against Counterclaim Defendant, and issue an order:

- A. Dismissing Counterclaim Defendant's Complaint with prejudice;
- B. Denying Counterclaim Defendant any of the relief it requested in the Complaint;
- C. Declaring all claims of the '427, '474, '998, '283, '607, and '608 patents invalid and/or unenforceable;
- D. Declaring that the filing of ANDA No. 208522 did not infringe any valid and enforceable claim of the '427, '474, '998, '283, '607, and '608 patents;

- E. Declaring that the manufacture, use, sale, offer for sale, and/or importation into the United States of the products described in ANDA No. 208522 would not directly or indirectly infringe any valid and enforceable claim of the '427, '474, '998, '283, '607, and '608 patents;
- F. Declaring that the 30-month time period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;
- G. Declaring this case exceptional in favor of Actavis FL pursuant to 35 U.S.C. § 285;
- H. Awarding costs and attorneys' fees to Actavis FL; and
- I. Awarding Actavis FL such other and further relief as the Court deems just and proper.

Dated: November 19, 2015

CONNELL FOLEY LLP
Attorneys for Defendants
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Actavis Pharma, Inc.

/s/ Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any other court or of any pending arbitration or administration proceeding.

Dated: November 19, 2015

/s/ Liza M. Walsh

Liza M. Walsh

CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, Defendants, through their attorneys, certify that the above captioned matter is not subject to compulsory arbitration.

Dated: November 19, 2015

/s/ Liza M. Walsh
Liza M. Walsh